From:	Odenkirchen, Edward
To:	OPP EFED Tracking Team
Cc:	Montague, Kathryn V.; Kenny, Daniel; Schmid, Emily; Sankula, Sujatha; Radtke, Meghan
Subject:	Document for Close out
Date:	Wednesday, September 17, 2014 9:02:15 AM
Attachments:	051505_422717_S3NCHEM_09_16_14_Addendum For ESA Indiana Bat Revision.pdf

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Please see attached document for 2,4-D choline
files….051505_422717_S3NCHEM_09_16_14_Addendum For ESA Indiana Bat Revision

Thanks

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

PC Code: 051505
DP Barcode: 422717
Date: September 17, 2014

MEMORANDUM

Subject: Addendum to 2,4-D Choline Salt Section 3 Risk Assessment: Refined Endangered Species Assessment, Based on Revised Toxicity Value, for Indiana Bat for Proposed New Uses on 2,4-D -Tolerant Corn and Soybean

To: Emily Schmid, Risk Manager Reviewer
Kathryn Montague, Product Manager Team 23
Dan Kenny, Branch Chief
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

From: Edward Odenkirchen, Ph.D., Senior Science Advisor 9/17/14
Meghan Radtke, Ph.D., Biologist (Acting Risk Assessment Process Leader) 9/17/14
Sujatha Sankula, Ph.D., Branch Chief 9/17/14
Environmental Risk Branch 1
Environmental Fate and Effects Division (7507P)
Office of Pesticide Programs

The Environmental Fate and Effects Division (EFED) issued a screening level risk assessment for a Federal action involving proposed new uses of the 2,4-D choline salt on herbicide(2,4-D)-tolerant corn and soybean on January 15, 2013 (DP 400223, 400230, 400234, 400237, 405028, 405812); an amendment to the assessment was issued on June 13, 2013 (DP 411614) that updated plant toxicity endpoints and spray drift buffer distances. An addendum to the assessment was issued on February 12, 2014 (DP 418022) that considered listed species within six states (IL, IN, IA, OH, SD, and WI). The addendum to the risk assessment issued on February 12, 2014 (DP 418022) included a comprehensive review of available rat reproduction and developmental toxicity data that established a chronic effects threshold of 55 mg/kg/day. The addendum only used this endpoint in a probabilistic risk estimation model refinement. EFED concludes that the NOAEL of 55 mg/kg/day is the appropriate screening level chronic effects threshold for mammals (scaled for bodyweight across the taxonomic group) that took into

account all lines of evidence on pharmacokinetics of 2,4-D in the rat test system , instead of the 5 mg/kg/day endpoint used in the previous assessments.

The remainder of this addendum is an effects determination for Indiana bat (*Myotis sodalis*) that reflects the Agency's expanded understanding of chronic toxicity in mammals by taking into account dynamics of 2,4-D in mammalian test systems in the risk screening process. The conclusions in this addendum do not change effects determinations made in DP 418022, but clarify toxicity endpoint use and verify the previous effects determination for the Indiana bat (*Myotis sodalis*) for the six states.

Indiana Bat Revised Assessment

The initial screening level risk assessment results for the Indiana bat were revised to account for the bat's biology as well as the expanded understanding of 2,4-D dynamics in mammalian test systems (i.e., the use of the 55 mg/kg/day chronic threshold). This 55 mg/kg-bw endpoint, was scaled to individual modeled bat body weights using the extrapolation technique described in T-REX .

Field metabolic rate kcal/day = $0.6167(5.4)^{0.862}$= 2.64 kcal/day (USEPA 1993, body weight reflects screening assumption for the Indiana bat)
Mass of prey consumed per day = 2.64 kcal/day /(1.7 kcal/g ww X 0.87AE) = 1.78 g/day
Mass of 2,4-D choline in insect diet = 226.56 mg/kg-ww from T-REX run
Mass of 2,4-D in daily diet = 1.78 g/day X 226.56 mg 2,4-D/kg-ww mammal prey X 0.001 = 0.40 mg/day
Daily dose in bat = 0.40mg 2,4-D/day/0.0054 = 74 mg/kg-bw/day
Indiana Bat NOAEL mg/kg-bw/day = 55 mg/kg-bw $(350/5.4)^{0.25}$ = 156.06 mg/kg-bw
RQ for chronic exposure for three applications, peak exposure number: RQ = 74/156.06 = 0.47

An RQ of 0.47 does not exceed the chronic LOC of 1.0; **consequently a "no effect" determination is concluded for the Indiana Bat.** Under this more scientifically defensible toxicity threshold scenario, the result would also indicate that a more probabilistic approach to the exposure modelling is of limited utility in understanding the potential for effects on the species.